

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Nº 07-CV-3397 (JFB) (ETB)

REXALL SUNDOWN, INC.,

Plaintiff,

VERSUS

PERRIGO CO.,

Defendant.

MEMORANDUM AND ORDER

September 10, 2009

JOSEPH F. BIANCO, District Judge:

Plaintiff Rexall Sundown, Inc. (hereinafter, “Rexall” or “plaintiff”) brings this action against Perrigo Company (hereinafter, “Perrigo” or “defendant”), claiming violations of the Lanham Act, 15 U.S.C. § 1051, *et seq.* and state law. Perrigo brings counterclaims against Rexall also claiming violations of the Lanham Act.

Rexall is the manufacturer of Osteo Bi-Flex products, which is a brand of nutritional supplement for joint care containing the ingredients Glucosamine and Chondroitin. Rexall alleges that Perrigo, a competitor that manufactures Glucosamine Chondroitin supplements for sale as leading store brands, is using false and misleading “Compare to Statements” on certain products – such as “Compare to Osteo Bi-Flex Glucosamine with Joint Shield Ingredients,” “Compare to Osteo Bi-Flex Ingredients,” or “Compare to Osteo Bi-Flex” – in violation of the Lanham Act and

state law. In short, Rexall contends that these advertising statements are false and misleading to consumers because the statements allegedly convey that Perrigo’s generic nutritional supplements are equivalent to Rexall’s Osteo Bi-Flex products even though, according to Rexall, the formulation of Perrigo’s products is materially different from Osteo Bi-Flex. Perrigo disputes these claims.

In its counterclaims, Perrigo alleges that Rexall’s use of various false and misleading statements on its Osteo Bi-Flex products – namely, “No. 1 Dr. Recommended Brand,” (Claim 1), “No. 1 Dr. Recommended Joint Care Brand,” (Claim 2), “Clinically Tested,” (Claim 3), “provides more pure Glucosamine as compared to Glucosamine Sulfate,” (Claim 4), “is 10 times more concentrated than typical Boswellia extracts,” (Claim 5) and the use of the Arthritis Foundation’s name and logo (Claim 6) – violates the Lanham Act and state law. Rexall disputes these claims.

Both parties now move for summary judgment on all of the opposing party's claims. For the reasons set forth below, the Court (1) denies defendant's summary judgment motion on plaintiff's claims in its entirety, and (2) grants in part and denies in part plaintiff's motion for summary judgment on defendant's counterclaims – namely, summary judgment is granted on Claims 1-4 and 6 and denied on Claim 5.

I. FACTS¹

The Court has taken the facts described below from the parties' depositions, affidavits, and exhibits, and from the Rule 56.1 statements of facts. Upon consideration of a motion for summary judgment, the Court shall construe the facts in the light most favorable to the non-moving party. *See Capobianco v. City of New York*, 422 F.3d 47, 50 (2d Cir. 2005).

Rexall markets Osteo Bi-Flex, a nutritional supplement containing the ingredients Glucosamine and Chondroitin that promotes joint comfort and range of motion in joints. (Pl.'s 56.1 ¶ 1.) In approximately 2006, Rexall introduced reformulated versions of Osteo Bi-Flex that include 5-LOXIN, a standardized extract of herb *Boswellia serrata* developed to provide enhanced joint-care benefits that have been documented in published, peer-reviewed research. (Pl.'s 56.1 ¶ 2.)

Perrigo has sold products bearing statements comparing such products to Osteo Bi-Flex, by name, since at least 2001. (Pl.'s 56.1 ¶ 13.)

A. Rexall's Claims

Plaintiff brings this action against defendant, on the basis of defendant's use of the statements "Compare to Osteo Bi-Flex," "Compare to Osteo Bi-Flex Ingredients," and "Compare to Osteo Bi-Flex Glucosamine Chondroitin MSM with Joint Shield Ingredients," and variations of these statements (the "Compare To Statements") in advertising the store brand Glucosamine Chondroitin Products it produces (the "Perrigo Products"), asserting that these statements constitute false and misleading advertising under the Lanham Act and New York State law. (Def.'s 56.1 ¶¶ 1-2.)

Rexall manufactures various Osteo Bi-Flex products. All of these products contain Glucosamine and Chondroitin, which have been shown to aid in joint lubrication, cartilage rebuilding, and joint comfort. (Def.'s 56.1 ¶ 9.) Some, but not all, Osteo Bi-Flex products contain an extract of *Boswellia serrata* known as 5-LOXIN. (*Id.*) The Advanced Double Strength and Advanced Triple Strength versions of Osteo Bi-Flex each contain 100 milligrams of 5-LOXIN. (*Id.*) Studies suggest that *Boswellia serrata* has anti-inflammatory effects, and can be used in the treatment of a variety of conditions. (Def.'s 56.1 ¶ 10.) There are at least six boswellic acids, including AKBA. (Rosenbush Decl. ¶¶ 3-11; Pl.'s Ex. 7.) Published scientific research has shown that AKBA is the most active of the boswellic acids. (Rosenbush Decl. ¶ 7; Pl.'s Ex. 2.) Typical *Boswellia serrata* extracts are comprised of 2-3% AKBA, but 5-LOXIN is

¹ Unless otherwise noted, where only one party's 56.1 Statement is cited, the facts are taken from that party's 56.1 Statement, and the other party does not dispute the fact asserted or has offered no admissible evidence to refute that fact.

standardized to no less than 30% AKBA. (Rosenbush Decl. ¶¶ 7-9.) 5-LOXIN contains reduced or non-existent amounts of the other boswellic acids.

Rexall commissioned a survey by Robert Klein (hereinafter, “Klein Survey”), which found that Perrigo’s Compare To Statements are understood by 29% of consumers as communicating a message that Perrigo Products are equivalent to Osteo Bi-Flex in terms of formulation and/or efficacy. (See Klein Decl. ¶¶ 26-28.)

Perrigo contends that the Compare To Statements are not false or misleading. Specifically, Perrigo has put forth evidence that “independent laboratories determined that the amounts of AKBA in the Perrigo Products were nearly identical to the amounts of AKBA in the Osteo Bi-Flex Products and these amounts would be considered equivalent when considering the margin of measurement uncertainty.” (Def.’s 56.1 ¶ 45.) Thus, according to Perrigo, “[b]ased on the results of either test, the products cannot be reasonably said to differ with respect to the amount of AKBA – the key differentiating factor between the products according to the Complaint.” (*Id.*)

Although Rexall does not dispute that the amounts of AKBA are nearly identical in the Perrigo Products and the Osteo Bi-Flex Products, Rexall disputes that the products are equivalent for two reasons. (Pl.’s Response to Def.’s 56.1 ¶ 45.) First, Rexall has submitted evidence that Osteo Bi-Flex has a much higher percentage of AKBA in relation to the total of boswellic acids in each product. (*Id.*) Second, Rexall contends that “the Perrigo Product contains twice the amount of beta boswellic acid, a compound that significantly *reduces* the anti-inflammatory activity of the

most active compound, AKBA” and thereby makes it less effective. (*Id.*) (emphasis added). Therefore, according to Rexall, “[t]he chemical differences revealed in these test results significantly impact the physiological activity of the parties’ supplements.” (*Id.*)

Based upon these tests and expert evidence, Rexall asserts that the “Compare To Statements” are impliedly false and misleading because the Perrigo Products are materially different from the Osteo Bi-Flex Products in formulation and efficacy. (Compl. ¶¶ 16-19.)

B. Perrigo’s Counter-Claims

Perrigo’s counter-claims assert that six statements used by Rexall in the advertising or packaging for Osteo Bi-Flex are false or misleading. These statements are:

1. Osteo Bi-Flex is the “No. 1 Dr. Recommended Brand” of Glucosamine and Chondroitin nutritional supplements among doctors who recommend a branded form of Glucosamine and Chondroitin (“Claim 1”).
2. Osteo Bi-Flex is the “No. 1 Dr. Recommended Joint Care Brand” of Glucosamine and Chondroitin nutritional supplements among doctors who recommend a branded form of Glucosamine and Chondroitin (“Claim 2”).
3. Osteo Bi-Flex has been “clinically tested” (“Claim 3”).
4. Osteo Bi-Flex “provides more pure Glucosamine as compared to Glucosamine Sulfate” (“Claim 4”).

5. Osteo Bi-Flex's key ingredient "is 10 times more concentrated than typical Boswellia extracts" ("Claim 5").

6. Osteo Bi-Flex treats, prevents, and/or cures arthritis ("Claim 6"). Defendant contends that this claim is conveyed to consumers through the numerous references to the Arthritis Foundation, arthritis treatment and prevention in packaging, print and Internet advertising for Osteo Bi-Flex products.

(Pl.'s 56.1 ¶ 3; Def.'s Response to Pl.'s 56.1 ¶ 3.) The Court will briefly summarize the evidence regarding each claim in turn.

1. "No. 1 Doctor Recommended Brand"

Rexall has promoted Osteo Bi-Flex as the "No. 1 Doctor Recommended Brand" of Glucosamine and Chondroitin nutritional supplements since the late 1990s. (Pl.'s 56.1 ¶ 4.) This claim is based on an ongoing independent survey of physicians called the National Disease and Therapeutic Index ("NDTI") that tracks the treatments recommended to patients by their physicians. (Pl.'s 56.1 ¶ 5.) "The quarterly results of the NDTI survey generated over many years, as confirmed by an independent consultant Rexall employs to monitor the survey results, have established that Osteo Bi-Flex is the most recommended, branded form of Glucosamine and Chondroitin nutritional supplements among doctors who recommend a branded form of such supplements." (Pl.'s 56.1 ¶ 6.)

However, Perrigo contends that the claim is false and misleading because those same reports reflect that a majority of doctors

simply recommended Glucosamine as treatment for joint problems, without naming a specific brand. (Marcotte Dec. Ex. 9.) Therefore, at times, only 10% of the doctors surveyed actually recommended Osteo Bi-Flex. (*Id.*) Rexall notes that it has always accompanied its claim as the "No. 1 Dr. Recommended Brand" with an explanatory note stating that such statement is "Based on the results of the National Disease and Therapeutic Index syndicated report among physicians who recommend a branded glucosamine/chondroitin or glucosamine supplement," followed by the date of a NDTI report confirming such ranking. (Pl.'s 56.1 ¶ 7.) Perrigo asserts that such an explanatory note is insufficient because the note "does not include any reference to the actual small percentage of doctors that recommended a brand instead of non-branded glucosamine chondroitin or glucosamine supplements." (Def.'s Response to Pl.'s 56.1 ¶ 7.)

Since Rexall first began promoting Osteo Bi-Flex as the "No. 1 Dr. Recommended Brand," Rexall has invested a significant amount of money and resources in marketing the brand to increase awareness of the product among consumers and health care providers in order to maintain Osteo Bi-Flex's status as the "No. 1 Dr. Recommended Brand." (Pl.'s 56.1 ¶ 8.) Rexall has spent more than \$45 million on print, television and electronic advertisements in which this claim has appeared. (Pl.'s 56.1 ¶ 9.) Rexall has sold millions of boxes of Osteo Bi-Flex each year, and, since as early as 1999, each box has included this claim on the principal display panel. (Pl.'s 56.1 ¶ 10.) Between July 2003 and April 2008, Rexall sold more than 22 million units of Osteo Bi-Flex in packaging bearing this claim. (Pl.'s 56.1 ¶ 11.)

Rexall contends that “Perrigo has had at least constructive knowledge for years that Rexall was prominently featuring Advertising Statement 1 on the packaging and in advertising for Osteo Bi-Flex but took no action to halt such use until after Rexall commenced this action.” (Pl.’s 56.1 ¶ 12; Kamil Decl. ¶¶ 6-9, Ex. 1-4; Walker Decl. ¶¶ 4-5, Ex. 1; Ewing Decl., Ex. 3 at 25.) Defendant, however, asserts that Perrigo did not have knowledge of the falsity of the claim until July 2007, when the National Advertising Division (hereinafter, “NAD”) of the Council of Better Business Bureaus issued a decision following its inquiry into Rexall’s advertising practices. (Def.’s Response to Pl.’s 56.1 ¶ 12; Marcotte Decl., Ex. 2 (NAD report substantiating Rexall’s use of its claim that Osteo Bi-Flex is the “No. 1 Dr. Recommended Brand,” but suggesting some modifications on its website to avoid confusion).)

2. “No. 1 Dr. Recommended Joint Care Brand”

In approximately 2004 or 2005, Rexall began referring to Osteo Bi-Flex as the “No. 1 Dr. Recommended Joint Care Brand” in advertisements and promotion for the product. (Pl.’s 56.1 ¶ 15.) This claim, however was not included in the packaging for Osteo Bi-Flex. (*Id.*)

Perrigo argues that this claim is false and misleading essentially for the same reasons articulated by Perrigo with respect to Claim 1 – namely, the claim (even with the explanatory note) does not include any reference to the small percentage of doctors who actually recommended Osteo Bi-Flex, as opposed to simply recommending a non-branded Glucosamine Chondroitin or Glucosamine supplement. (Def.’s Response

to Pl.’s 56.1 ¶ 16.) Thus, according to Perrigo, there is no evidence to support this claim.

Rexall disputes Perrigo’s position and also notes that it stopped using this claim in early 2008 and represents that it has no intention to resume its use. (Pl.’s 56.1 ¶ 17; Kamil Decl. ¶ 13.) Perrigo contends, however, that “[t]here is a likelihood that Rexall will resume making the . . . claim on its products as there is no existing Court order or express statement from Rexall that it will not make this claim in the future.” (Def.’s Response to Pl.’s 56.1 ¶ 17.)

3. “Clinically Tested”

Prior formulations of Osteo Bi-Flex have been the subject of human clinical testing. (Pl.’s 56.1 ¶ 18.) The ingredients Glucosamine and Chondroitin, as well as 5-LOXIN have also been the subject of human clinical testing. (*Id.*)

Although Perrigo does not dispute the above-referenced facts, it contends that the “clinically tested” claim made by Rexall is false and misleading. Specifically, Perrigo asserts that, “while there has been clinical testing for the ingredients of Osteo Bi-Flex . . . (Glucosamine, Chondroitin, and 5-LOXIN) and for prior formulations of Osteo Bi-Flex, the current formulation of Osteo Bi-Flex has never been clinically tested” and “Rexall does not specify anywhere on its box what Osteo Bi-Flex has actually been clinically tested for or what it has been proven to do.” (Def.’s Response to Pl.’s 56.1 ¶ 18.) (citations omitted).

Rexall notes that it ceased using this claim in early 2008 and represents that it has no intention of resuming its use. (Pl.’s 56.1 ¶ 19;

Okaro Decl. ¶¶ 4-7, Exh. 1-3.) Defendant argues, however, that there is a likelihood that will resume using this claim in the future. (Def.'s Response to Pl.'s 56.1 ¶ 19.)

4. More Pure Glucosamine as Compared to Glucosamine Sulfate

The form of Glucosamine used in Osteo Bi-Flex is Glucosamine HCl, which is more pure than Glucosamine sulfate. (Pl.'s 56.1 ¶¶ 20-21.) Members of NBTY, Rexall's parent company's Nutrition Department, analyzed Glucosamine HCl in 2005 and found that it contains at least 1.4 times more pure Glucosamine than Glucosamine Sulfate. (Pl.'s 56.1 ¶ 22.) Perrigo contends that the claim is false and misleading because Rexall never analyzed whether this fact would result in a performance benefit. (Def.'s Response to Pl.'s 56.1 ¶ 22; Marcotte Decl. Ex. 11, at 17:14-21; 20:13-21.)

Rexall disputes Perrigo's position and also notes that it ceased using this claim in early 2008 and has no intention to resume using it. (Pl.'s 56.1 ¶ 23; Okaro Decl. ¶¶ 10-11.) Defendant again contends that it is likely that plaintiff will resume using this claim, as there is nothing to prevent it from doing so. (Def.'s Response to Pl.'s 56.1 ¶ 23.)

5. 10 Times More Concentrated

Boswellia serrata is a tree found in India. (Pl.'s 56.1 ¶ 24.) Scientific literature demonstrates that the gum resin extracted from this tree is a potent inhibitor of the 5-lipoxygenase ("5-LOX") enzyme. (Plaintiff's 56.1 ¶ 25.) Inhibition of this enzyme has anti-inflammatory effects. (*Id.*) *Boswellia serrata* has historically been used to support joint health. (Pl.'s 56.1 ¶ 26.) *Boswellia serrata* extracts are made from a variety of boswellic

acids. (Pl.'s 56.1 ¶ 27.) Of these boswellic acids, 3-O-acetyl-11-keto-beta-boswellic acid ("AKBA") is the most potent inhibitor of the 5-LOX enzyme. (Pl.'s 56.1 ¶ 28.)

While typical *Boswellia serrata* extracts are comprised of 2-3% AKBA, 5-LOXIN is a *Boswellia serrata* extract that is standardized to no less than 30% AKBA. (Pl.'s 56.1 ¶ 29.) Therefore, when compared to typical *Boswellia serrata* extracts, 5-LOXIN has at least 10 times more AKBA. (*Id.*)

Perrigo commissioned a consumer survey about this claim (hereinafter, "Ossip Survey"). (Pl.'s 56.1 ¶ 30.) In this survey, participants were shown a "modified version of the front of an Osteo Bi-Flex box." (Marcotte Decl. Ex. 6, at 3.) Specifically, half of the respondents were shown a modified version of the side panel of an Osteo Bi-Flex box with the "10 Times More Concentrated" claim appearing on that panel, while the other half were shown the side panel with the claim deleted. (*Id.*) Participants were then asked to rate their interest in the product. (Pl.'s 56.1 ¶ 32.) Participants were also asked whether they thought the product was likely to be better, about the same, or not as good, as other dietary supplements containing Glucosamine, Chondroitin and MSM. (Def.'s Response to Pl.'s 56.1 ¶ 32.) The survey concluded that respondents that were shown the packaging with the "10 Times More Concentrated" claim were more likely to think that Osteo Bi-Flex would be better than other dietary supplements containing Glucosamine, Chondroitin and MSM. (*Id.*) Specifically, the survey found that "[o]f those exposed to the claim, 55% thought the product would be better, compared with 38% among those not exposed to the . . . claim." (*Id.*) These results showed no statistically significant difference between the two groups in terms of their

interest in purchasing Osteo Bi-Flex. (Pl.’s 56.1 ¶ 33.)

Perrigo argues that the statement “conveys the false and misleading claim that because consumers are getting significantly more 3-acetyl-11-keto-beta-boswellic acids (AKBA) by taking [Rexall’s] concentrated product as opposed to other typical Boswellia extracts, they would, correspondingly, experience some greater performance benefit (i.e. with respect to efficacy on knee comfort and mobility and increased walking distance, etc.) or that Osteo Bi-Flex is otherwise superior to typical Boswellia extracts simply by the fact of being 10 times more concentrated.” (Def.’s Answer and Counterclaims ¶ 32.) Rexall disputes Perrigo’s position on this claim.

6. Arthritis Claims

Rexall has supported the work of the Arthritis Foundation since the late 1990s by supporting its activities and contributing hundreds of thousands of dollars annually to it. (Pl.’s 56.1 ¶ 34.) Rexall has been authorized by the foundation to display its trademarked logo on the packaging and advertising for Osteo Bi-Flex. (Pl.’s 56.1 ¶ 35.) Rexall has used this logo in its advertising and on its packaging since the late 1990s. (Pl.’s 56.1 ¶ 36.) Rexall referred to the logo as an “implied endorsement” twice in its 2002-2005 strategic plan. (Def.’s Response to Pl.’s 56.1 ¶ 36; Marcotte Decl. Ex. 12.)

Rexall contends that every advertisement for and every box of Osteo Bi-Flex contains the statement that “this product is not intended to diagnose, treat, cure or prevent any disease.” (Kamil Decl. ¶15.) Perrigo disputes this, contending that “the evidentiary material cited in Rexall’s supporting Declarations does

not support [this assertion]. Many of the examples of Osteo Bi-Flex packaging and advertising that were included as exhibits to Rexall’s supporting Declarations do not bear the statement.” (Def.’s Response to Pl.’s 56.1 ¶ 37.) (citations omitted). Perrigo further asserts that, where the disclaimer does appear, it does not appear close to the logo and is not linked to the logo by an asterisk or other device. (*Id.*) Thus, Perrigo claims that, “[t]hrough numerous references to the Arthritis Foundation, arthritis treatment and prevention in packaging, print and Internet advertising (the “Arthritis Claims”), [Rexall’s] advertising conveys the false and misleading claim that Osteo Bi-Flex treats, prevents, and/or cures arthritis.” (Def.’s Answer and Counterclaims ¶ 37.)

C. National Advertising Division

On July 12, 2008, the NAD issued findings about the accuracy of Rexall’s Claims. This report explains that “[a]s part of NAD’s routine monitoring program, NAD requested substantiation for product description, exclusivity and Dr. Recommended claims made in Internet advertising and product packaging by Rexall Sundown, Inc. for its Osteo Bi-Flex dietary supplement containing glucosamine and chondroitin.” (Marcotte Decl., Ex. 2, at 1.) Of the Claims at issue in this lawsuit, the NAD’s inquiry included all but Claim 6.

The NAD did not find any of the statements to be literally false. However, the NAD reached the following conclusions and made the following recommendations:

NAD determined that the advertiser’s “#1 Doctor Recommended Brand” claim was substantiated, however, NAD

recommended that the advertiser modify the accompanying disclosure as discussed herein so as to make it more prominent and easier to read. NAD further recommended that the advertiser's website be modified, as detailed in the Decision, to avoid conveying any implied message attributing any specific reason for its "#1 Doctor Recommended Brand" status. Likewise, NAD recommended that the advertiser modify its "#1 Doctor Recommended *Joint Care Brand****", as outlined herein, to more narrowly and accurately reflect the findings of the NDTI survey upon which it is based.

NAD determined that a reasonable basis existed for the advertiser's "clinically tested" claims with respect to the therapeutic effects of glucosamine and chondroitin but recommended that the advertiser discontinue use of this claim in conjunction with its Good Manufacturing Practices.

NAD further concluded that the advertiser provided a reasonable basis for its claim that "Osteo Bi-Flex is the only brand to feature the revolutionary formulation of ingredients in Joint Shield™, which work to guard against the action of enzymes that affect joint health."

NAD recommended that the advertiser modify its claims regarding the inclusion of the HCl form of glucosamine in its product to limit it to the fact that it "utilizes the HCl form of Glucosamine" without

further comparative language, or otherwise clearly disclose that its inclusion of 1.4 times more pure glucosamine has not been proven to result in superior performance.

Similarly, NAD recommended that the advertiser modify its claims regarding, 5-LOXIN in its Joint Shield, to more narrowly limit it to the inclusion of "a potent [concentrated] extract of *Boswellia serrata* called 5-LOXIN", without a comparative reference to the *Boswellia* in Osteo Bi-Flex being "10 times more concentrated than the typical *Boswellia* extracts."

Lastly, NAD recommended that the advertisers discontinue use of the term "Double Strength" and "Triple Strength" on the respective product names, "Osteo Bi-Flex Advanced Double Strength" and "Osteo Bi-Flex Advanced Triple Strength."

(Marcotte Decl., Ex. 2, at 15-16.)

II. PROCEDURAL HISTORY

Plaintiff filed this action on August 16, 2007. Defendant filed its answer on September 20, 2007. Defendant filed its motion for summary judgment on December 19, 2008. Plaintiff filed its response to defendant's motion and its own motion for summary judgment on January 9, 2009. Defendant filed its opposition to plaintiff's motion and its reply in support of its own motion on February 6, 2009. Plaintiff filed its reply in support of its motion on February 17, 2009. Oral argument was heard on May 1,

2009. All of the parties' submissions have been considered.

III. STANDARD OF REVIEW

The standards for summary judgment are well settled. Pursuant to Federal Rule of Civil Procedure 56(c), a court may not grant a motion for summary judgment unless "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Globecon Group, LLC v. Hartford Fire Ins. Co.*, 434 F.3d 165, 170 (2d Cir. 2006). The moving party bears the burden of showing that he or she is entitled to summary judgment. *See Huminski v. Corsones*, 396 F.3d 53, 69 (2d Cir. 2004). The court "is not to weigh the evidence but is instead required to view the evidence in the light most favorable to the party opposing summary judgment, to draw all reasonable inferences in favor of that party, and to eschew credibility assessments." *Amnesty Am. v. Town of W. Hartford*, 361 F.3d 113, 122 (2d Cir. 2004); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) (holding that summary judgment is unwarranted if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party").

Once the moving party has met its burden, the opposing party "must do more than simply show that there is some metaphysical doubt as to the material facts [T]he nonmoving party must come forward with specific facts showing that there is a genuine issue for trial." *Caldarola v. Calabrese*, 298 F.3d 156, 160 (2d Cir. 2002) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S.

574, 586-87 (1986)). As the Supreme Court stated in *Anderson*, "[i]f the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." 477 U.S. at 249-50 (citations omitted). Indeed, "the mere existence of *some* alleged factual dispute between the parties" alone will not defeat a properly supported motion for summary judgment. *Id.* at 247-48. Thus, the nonmoving party may not rest upon mere conclusory allegations or denials, but must set forth "concrete particulars" showing that a trial is needed. *R.G. Group, Inc. v. Horn & Hardart Co.*, 751 F.2d 69, 77 (2d Cir. 1984) (internal quotations omitted); *St. Paul Mercury Ins. Co. v. Pepsi-Cola Bottling Co. of N.Y., Inc.*, 04 civ 360 (DGT), 2007 U.S. Dist. LEXIS 56884, at *18 (E.D.N.Y. Aug. 2, 2007). Accordingly, it is insufficient for a party opposing summary judgment "merely to assert a conclusion without supplying supporting arguments or facts." *BellSouth Telecomms., Inc. v. W.R. Grace & Co.*, 77 F.3d 603, 615 (2d Cir. 1996) (internal quotations omitted).

IV. DISCUSSION

A. Rexall's Claims

Rexall alleges that Perrigo is using false and misleading "Compare to Statements" on certain products – such as "Compare to Osteo Bi-Flex Glucosamine with Joint Shield Ingredients," "Compare to Osteo Bi-Flex Ingredients," or "Compare to Osteo Bi-Flex" – in violation of the Lanham Act and state law. As set forth below, the Court concludes that summary judgment on these claims is unwarranted because Rexall has set forth sufficient evidence to raise genuine issues of material fact as to the essential elements of these federal and state claims.

1. Lanham Act Claim

Section 43(a) of the Lanham Act provides:

Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which-

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1). To establish a claim under 15 U.S.C. § 1125, "a plaintiff must prove the following elements: 1) the defendant has made a false or misleading statement; 2) the false or misleading statement has actually deceived or has the capacity to deceive a substantial portion of the intended audience; 3) the deception is material in that it is likely to influence purchasing decisions; 4) there is a likelihood of injury to plaintiff, such as declining sales or loss of goodwill; and 5) the goods traveled in interstate commerce." *Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp.*, 348 F. Supp. 2d 165, 177-78 (S.D.N.Y. 2004); *accord Autoinfo, Inc. v. Hollander Pub. Co.*, No. 90-CV-6994 (JSM), 1991 WL 64190, at *4 (S.D.N.Y. Apr. 17, 1991).

In addition to the false advertising claim under the Lanham Act, Rexall asserts three other causes of action for false advertising under New York law: (1) false advertising in violation of New York General Business Law § 350; (2) deceptive acts and practices in violation of New York General Business Law § 349; and (3) unfair competition in violation of New York State common law. Perrigo's counterclaims are also brought under the same theories of liability under federal and state law. However, the state causes of action are analyzed under the same substantive standard as the Lanham Act claims. *See Twentieth Century Fox Film Corp. v. Marvel Enters., Inc.*, 155 F. Supp. 2d 1, 25 (S.D.N.Y. 2001) (noting that standards for New York unfair competition and Lanham Act claims are substantively similar).

With respect to its motion for summary judgment on Rexall's claims, Perrigo argues the following: (1) its Compare To Statements are not actionable as a matter of law under the Lanham Act because they are not descriptions or representations of fact; and (2) even if the statements were actionable, Rexall has put forth (a) insufficient and inadmissible expert evidence to support a finding that the statements have the ability to deceive the intended audience, (b) insufficient evidence to support a finding that the Compare To Statements are material to customers, and (c) insufficient evidence to support a finding of falsity. The Court will address each issue in turn.

a. Whether the Compare To Statements are Actionable as a Matter of Law

Perrigo argues that summary judgment is appropriate on plaintiff's claims because the Compare To Statements are not actionable as a matter of law because the statements are not descriptions or representations of fact, but

rather are simply non-actionable, general invitations to compare products. In particular, Perrigo contends that only specific, verifiable statements are actionable under the Lanham Act; not “broad, vague, and commendatory language,” and that its Compare To Statements fall within the second category. (Def.’s Mem. at 5 (citation omitted).) As set forth below, after reviewing the Compare To Statements in the context in which it appeared, the Court cannot conclude that the statements are not actionable as a matter of law.

There are two theories of recovery under Section 43(a) of the Lanham Act. “First, the plaintiff can demonstrate that the challenged advertisement is literally false, *i.e.*, false on its face. . . . Alternatively, a plaintiff can show that the advertisement, while not literally false, is nevertheless likely to mislead or confuse consumers.” *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 153 (2d Cir. 2007). Here, Rexall’s claims are based “exclusively on a theory of implied falsity.” (Pl.’s Opp. Mem. at 5.) Rexall contends that defendant’s Compare To Statements, “in the specific packaging and product context in which they appear, communicate to consumers that the Perrigo Products are equivalent to Osteo Bi-Flex in terms of formulation and efficacy, when they are in fact materially different.” (Pl.’s Opp. Mem. at 9-10.) In response, Perrigo contends that the Compare To Statements are mere puffery and, therefore, not actionable. “Whether an alleged misrepresentation is an actionable statement of fact or mere puffery is a matter of law.” *Fl. Breckenridge, Inc. v. Solvay Pharm. Inc.*, No. 97-CV-8417, 1998 WL 468753, at *8 (S.D. Fla. Mar. 18, 1998).

As a threshold matter, to the extent that Perrigo suggests that “compare to” statements are never actionable, the Court disagrees. The

Court recognizes that the mere phrase “compare to” another product, without more, could merely be a non-actionable, general invitation to consumers to compare products, rather than constitute an actionable assertion of fact that can be verified or substantiated. However, that does not mean that all “compare to” statements are not actionable. “Compare to” statements, depending on their wording and context, may convey more than a general invitation to compare and, instead, convey a specific assertion of measurable fact, such as the same ingredients or efficacy. Under such circumstances, the statements are actionable. *See, e.g., Clorox Co. P.R. v. Proctor & Gamble Commercial Co.*, 228 F.3d 24, 37 (1st Cir. 2000) (finding actionable an advertisement inviting customers to “Compare to your detergent . . . Whiter is not possible”); *see also Axcen Scandipharm Inc. v. Ethex Corp.*, 585 F. Supp. 2d 1067, 1083 (D. Minn. 2007) (finding that plaintiff could succeed on its claims that its product was an alternative to defendant’s product and inviting a comparison between the two products “if it can prove that the Defendants’ advertising suggests that [the products] contain the same ingredients, in the same quantities, . . . when in fact they do not”).

In order to make this determination, the “compare to” statements must be analyzed in their entire context. *See Avis Rent A Car Sys., Inc. v. The Hertz Corp.*, 782 F.2d 381, 385 (2d Cir. 1986) (“Fundamental to any task of interpretation is the principle that text must yield to context. . . . [Therefore,] a court must consider the advertisement in its entirety and not . . . engage in disputatious dissection. The entire mosaic should be viewed rather than each tile separately.”) (internal citation and quotation marks omitted). After reviewing the evidence in the instant case, the Court cannot conclude that the Compare To Statements are mere puffery such that

summary judgment is warranted; rather, the statements, when considered in context, could be understood as messages of equivalence as to formulation and efficacy of the products. First, most of the Compare To Statements themselves do not simply invite a comparison of the products, but rather invite a comparison of the products' ingredients – such as “Compare to Osteo Bi-Flex Glucosamine with Joint Shield Ingredients,” “Compare to Osteo Bi-Flex Ingredients” – which is more likely to convey to a consumer that the two products share the same ingredient formulations and/or efficacy. Second, the Compare To Statements on Perrigo's packaging are in close proximity to, and sometimes directly adjacent to, performance claims, most notably “Formulated to Help: With Joint Comfort, Rebuild Cartilage & Lubricate Joints,” which could communicate a message of functional equivalence in certain respects. Third, there is evidence that the products at issue are likely to be shelved near each other in stores, making it more likely that a consumer would understand the Perrigo Products to be equivalent to the national brand with which they are being compared. In fact, in support of this argument, plaintiff cites to Perrigo's sponsored website, which states:

In most food and drug stores, you can look to the right of an advertised brand on the store shelf to find the national brand equivalent (store brand). Compare the active ingredient chart found on the back of the two packages and you will see that they are equal with regard to active ingredient and potency. The only differences between the two products may be the inactive ingredients, such as the colors, etc., and the price.

(Pl.'s Mem. at 15; Ewing Decl. Exs. 13 & 14.) Fourth, much of the text on the side and rear

panels of the Perrigo Products are either *verbatim* or in substantial part from the prior packaging for Osteo Bi-Flex.² In short, the Court cannot conclude that the Compare To Statements, in the circumstances of this case, are non-actionable puffery under the Lanham Act; rather, a jury must decide whether the Compare To Statements convey a false message of equivalence as to formulation and efficacy.³

² Rexall also argues that a letter Perrigo drafted to its customers after Rexall reformulated its product to contain *Boswellia serrata* is evidence that defendant intended the Compare To Statements to communicate a message of equivalency. The letter stated “Osteo BiFlex has recently reformulated their entire product line to include several different ingredients including Hyaluronic acid, MSM and Botsewellia [sic] Serrata. Therefore your existing formulas for the Triple Strength and Double Strength NBEs [National Brand Equivalents] are no longer equivalent and we need to revise the front panel label copy to remove the ‘Compare to Osteo Bi Flex’ statement.” (Ewing Decl., Ex. 17.) However, it is unclear whether this letter was sent and defendant's subjective intent is irrelevant on whether, as a matter of law, the Compare To Statements are actionable descriptions or statements of fact. Thus, the Court has not considered this letter on that issue.

³ Defendant argues that plaintiff is judicially estopped from arguing that the Compare To Statements are actionable under the Lanham Act because plaintiff took a contrary position in *Zoller Labs v. NBTY, Inc.*, No. 03-4252, 111 Fed Appx. 978, 2004 WL 2288152 (10th Cir. Oct. 12, 2004). The Court disagrees. In *Zoller*, NBTY, Rexall's parent company, defended the advertising for its product ZN-3, which included the statement “Compare to the Ingredients of Zantrex-3,” against Zoller's argument that such a claim was literally false and, therefore, actionable under the Lanham Act. There is no indication in the *Zoller* opinion that NBTY contended that no “compare to” statements are actionable under the Lanham

This Court's analysis is consistent with that of numerous other courts who have found "compare to" statements to be actionable given the nature of the statements and the context. *See, e.g., Nutrition & Fitness, Inc. v. Mark Nutritionals, Inc.*, 202 F. Supp. 2d 431, 435-36 (M.D.N.C. 2002) ("Plaintiff maintains that the 'Compare to Body Solutions' statement on its own products does not make a detailed or specified assertion of measurable fact. As such, Plaintiff contends that the statement Defendants complain of is merely nonactionable 'puffery.' The court disagrees. This is not an instance where the alleged false advertising claims are broad assertions of superiority in the field. Instead, by referencing a particular competing product, that is, the Body Solutions line, Plaintiff's invitation to 'compare' does not qualify as a vague claim of superiority. Unlike more subjective terms often used in advertising, 'compare' suggests that a product's performance has in fact been tested and

Act, and, in fact, the case was brought under a theory of literal falsity, not implied falsity, so even if NBTY had contended that no "compare to" statements could be literally false, that would be a different issue from the one at hand. Further, plaintiff in *Zoller* failed to put forth any evidence that consumers understood the "compare to" statement in that case to communicate an unambiguous message of equivalence to consumers. *See Time Warner Cable*, 497 F.3d at 158 ("only an unambiguous message can be literally false"). In contrast, in the instant action, Rexall is not arguing that all "compare to" statements are actionable or, even, that defendant's Compare To Statements are literally false. Instead, Rexall is arguing that the Compare To Statements in the particular context of the instant case are actionable under a theory of implied falsity. In short, the Court finds no basis for the application of judicial estoppel to Rexall's position in the instant case.

verified. Although 'compare to Body Solutions' by itself is not a false statement, Defendant alleges that the statement is misleading in that it leads consumers to believe that Plaintiff's products have been tested and are equivalent in efficacy or content with the Body Solutions line when they in fact are not." (citations omitted); *see also Cartier, Inc. v. Deziner Wholesale, L.L.C.*, No. 98-CV-4947 (RLC), 2000 WL 347171, at *4-5 (S.D.N.Y. Apr. 3, 2000) (denying summary judgment on a false advertising claim where product's label invited customers to compare prices, quality, and style).

b. Evidence of Actual or Likely Deception

Perrigo argues that, even if the Compare To Statements are potentially actionable under the Lanham Act under a theory of implied falsity, summary judgment is still warranted because Rexall's extrinsic evidence to support a finding of actual or likely deception of consumers is fatally flawed and inadmissible. As set forth below, the Court concludes that the evidence is admissible and is sufficient to raise genuine issues of material fact as to the likelihood of consumer deception to survive summary judgment.

It is well settled that, when bringing suit on a theory of implied falsity, a plaintiff must provide extrinsic evidence to support a finding that consumers do take away the misleading message alleged. *See Johnson & Johnson*Merck Consumer Pharm. Co. v. SmithKline Beecham Corp.*, 960 F.2d 294, 297 (2d Cir. 1992) ("Where, as here, a plaintiff's theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged commercials tend to mislead or confuse consumers."); *see also The Procter & Gamble Co. v. Ultreo, Inc.*, 574 F. Supp. 2d

339, 345-46 (S.D.N.Y. 2008) (“[T]he success of a plaintiff’s implied falsity claim usually turns on the persuasiveness of a consumer survey that shows that a substantial percentage of consumers are taking away the message that the plaintiff contends the advertising is conveying. Cases have held that 20% constitutes a substantial percentage of consumers. Survey results are useful and have ‘evidentiary value’ if the surveys are properly designed and objectively and fairly conducted—for example, they employ ‘filters’ to screen out individuals whose responses may distort the results; the questions are directed to ‘the real issues’; and the questions are not leading or suggestive.”) (internal citations and quotation marks omitted). As the Second Circuit has explained:

It is not for the judge to determine, based solely upon his or her own intuitive reaction, whether the advertisement is deceptive. Rather, as we have reiterated in the past, “[t]he question in such cases is – what does the person to whom the advertisement is addressed find to be the message?” *Am. Home Products Corp.*, 577 F.2d at 166 (quoting *Am. Brands, Inc. v. R.J. Reynolds Co.*, 413 F. Supp. 1352, 1357 (S.D.N.Y. 1976)). That is, what does the public perceive the message to be?

*Johnson & Johnson*Merck*, 960 F.2d at 297-98 (emphasis in original).

In the instant case, Rexall has put forth evidence that consumers understand the Compare To Statements to convey that Perrigo’s Products are equivalent to Osteo Bi-Flex. Specifically, Rexall hired Robert Klein, who has “worked for over three decades in the field of market research pertaining to advertising and promotions, including extensive experience in designing, conducting

and evaluating consumer survey research for consumer product companies and for use in litigation, . . . to design and conduct a consumer survey that would measure consumer perceptions of a ‘Compare To’ statement referencing Osteo Bi-Flex nutritional supplements that appears on the labeling of a store-brand version of Osteo Bi-Flex manufactured by defendant Perrigo Company and sold at Walgreens.” (Klein Decl. ¶¶ 1, 3.) The survey was conducted “among approximately 400 respondents . . . who were potential purchasers of dietary supplements for joint care.” (Klein Decl. ¶ 5.) As a result of the survey, Klein found that 41% of all of the respondents in the Test Group (a group shown the Perrigo Product with a banner that states “Compare to Osteo Bi-Flex Glucosamine Chondroitin MSM with Joint Shield Ingredients”) and 16% of all of the respondents in the Control Group (a group shown the Perrigo product with a banner that states “Different from Osteo Bi-Flex Glucosamine Chondroitin MSM with Joint Shield Ingredients”) believe that the Perrigo Products provided the same joint care benefits as Osteo Bi-Flex. (Klein Decl. ¶ 26.) The survey revealed that 47% of the Test Group believed that the products either provided the same joint care benefits *or* contained the same ingredients, while 18% of the Control Group believed either of those contentions. (Klein Decl. ¶ 27.)

Perrino contends that Rexall’s survey is inadmissible because it is fatally flawed and, therefore, Klein’s Report should not be considered by this Court.⁴ As set forth below,

⁴ Perrigo did not request a hearing on this issue. The Court finds that no hearing is necessary at this juncture because Perrino’s objections are based on the written materials, rather than any disputed issues that need to be decided at a hearing. *See Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244,

the Court finds that the Klein Report is admissible under *Daubert* and is sufficient to raise genuine issues of fact to survive summary judgment on the issue of whether the Compare To Statements create a false message of product equivalence in terms of ingredients and/or efficacy that is likely to deceive consumers.

In deciding whether a motion for summary judgment should be granted, a district court may only consider admissible evidence. *See Nora Bevs., Inc., v. Perrier Group of Am., Inc.*, 164 F.3d 736, 746 (2d Cir. 1998) (stating that on summary judgment motion, “[a] district court properly considers only evidence that would be admissible at trial”); *accord Tamarin v. Adam Caterers, Inc.*, 13 F.3d 51, 53 (2d Cir. 1993). Thus, as the Second Circuit has explained, it is the proper role of the district court to consider the admissibility of expert testimony in determining whether summary judgment is warranted:

Because the purpose of summary judgment is to weed out cases in which ‘there is no genuine issue as

248-49 (6th Cir.2001) (holding that district court was not required to hold *Daubert* hearing before excluding evidence); *Oddi v. Ford Motor Co.*, 234 F.3d 136, 154-55 (3d Cir. 2000) (rejecting argument that *Daubert* hearing was required where court had reviewed record which included two depositions, a declaration, and an expert report); *see also Capellupo v. Nassau Health Care Corp.*, No. 06-CV-4922 (JFB), 2009 WL 1705749, at *9 n.10 (E.D.N.Y. June 16, 2009) (finding *Daubert* hearing unnecessary); *Colon v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 71 (S.D.N.Y. 2001) (“Nothing in *Daubert*, or any other Supreme Court or Second Circuit case, mandates that the district court hold a *Daubert* hearing before ruling on the admissibility of expert testimony, even where such ruling is dispositive of a summary judgment motion.”).

to any material fact and . . . the moving party is entitled to a judgment as a matter of law,’ Fed. R. Civ. P. 56(c), it is appropriate for district courts to decide questions regarding the admissibility of evidence on summary judgment. Although disputes as to the validity of the underlying data go to the weight of the evidence, and are for the fact-finder to resolve, questions of admissibility are properly resolved by the court. The resolution of evidentiary questions on summary judgment conserves the resources of the parties, the court, and the jury.

Raskin v. Wyatt Co., 125 F.3d 55, 66 (2d Cir. 1997) (internal citations and quotation marks omitted). In other words, “[t]he court performs the same role at the summary judgment phase as at trial; an expert’s report is not a talisman against summary judgment.” *Id.* at 66. Thus, if the expert testimony is excluded as inadmissible under the Rule 702 framework articulated in *Daubert* and its progeny, the summary judgment determination is made by the district court on a record that does not contain that evidence. *Id.* at 66-67. Such an analysis must be conducted even if precluding the expert testimony would be outcome determinative. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142-43 (1997). Accordingly, the Court must examine the admissibility of plaintiff’s expert testimony in ruling on defendant’s motion for summary judgment.

The admissibility of expert testimony is analyzed under Rule 702 of the Federal Rules of Evidence, which provides:

If scientific, technical, or other specialized knowledge will assist the

trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Thus, under Rule 702, the district court must make several determinations before allowing expert testimony: (1) whether the witness is qualified to be an expert; (2) whether the opinion is based upon reliable data and methodology; and (3) whether the expert's testimony on a particular issue will assist the trier of fact. *See Nimely v. City of N.Y.*, 414 F.3d 381, 397 (2d Cir. 2005). Because defendant has only challenged the admissibility of the survey and Klein's testimony relying on it under the second prong of the *Nimely* inquiry, the Court will proceed to the question of whether that report adequately depends upon "reliable data and methodology."

With respect to reliability, "the district court should consider the indicia of reliability identified in Rule 702, namely, (1) that the testimony is grounded on sufficient facts or data; (2) that the testimony is the product of reliable principles and methods; and (3) that the witness has applied the principles and methods reliably to the facts of the case." *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007) (quoting *Amorgianos v. Nat'l R.R. Passenger Corp. (AMTRAK)*, 303 F.3d 256, 266 (2d Cir. 2002) (internal quotation marks omitted)). Moreover, in addition to these criteria for determining whether the

methodology is reliable, Rule 702 also requires that there be a sufficiently reliable connection between the methodology and the expert's conclusions for such conclusions to be admissible. *See Gen. Elec. Co.*, 522 U.S. at 146 ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."); *Amorgianos*, 303 F.3d at 266 ("[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony.").

The proponent of the expert testimony bears the burden of establishing the admissibility of such testimony under the *Daubert* framework by a preponderance of the evidence standard. *See Daubert*, 509 U.S. at 593 n.10 ("These matters should be established by a preponderance of proof.") (citing *Bourjaily v. United States*, 483 U.S. 171, 175-76 (1987)); *see also* Fed. R. Evid. 702 advisory committee's note ("[T]he admissibility of all expert testimony is governed by the principles of Rule 104(a). Under that Rule, the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence."). Rexall has put forth evidence that Klein is an expert in the field of consumer surveying, that the survey was designed to determine whether consumers understood the Compare To Statements to be assertions of equivalency, and that the results derived from the survey reliably answered that question.

Perrigo argues that the survey used an improper control statement,⁵ failed to properly analyze and validate the data,⁶ and failed to recreate marketplace conditions.⁷ Klein has offered explanations and counter-arguments to all of these critiques in his declaration. For example, with respect to the objection

⁵ Specifically, Perrigo argues that the “different from” statement is not a statement used in the marketplace and that it, rather than “shar[ing] as many characteristics with the experimental stimulus as possible, with the key exception of the characteristic whose influence is being assessed, . . . it introduced a completely new characteristic in the form of a statement having a meaning wholly different than that of the Compare To Statement – one that made an explicit, factual product claim rather than a suggestion for consumer action, and one freighted with Rexall’s hoped-for interpretation of the Compare To Statement.” (Def.’s Mem. at 15.) Perrigo argues that this created a biased result, and that the survey simply should have removed the banner for the control group. (*Id.* at 16.) Perrigo further contends that the control was flawed because it was not “double-blind.” (*Id.*)

⁶ Perrigo argues that the open-ended questions that were asked to the survey participants were ignored and that the results of the survey rely entirely on two close-ended questions. (Def.’s Mem. at 17.) Perrigo contends that the failure to analyze the open-ended responses yielded flawed results. (*Id.* at 17-18.) Perrigo further argues that the validation of the survey that Klein conducted suggests pervasive problems with the integrity of the survey. (*Id.*)

⁷ Perrigo contends that survey participants were deprived of information they would have in ordinary marketplace conditions. (Def.’s Mem. at 18-20.) For example, participants were shown print outs from defendant’s website, rather than the actual site and, therefore, did not see the web address. (*Id.* at 18-19.) Further, the participants were only shown the Perrigo product and were not able to see the Osteo Bi-Flex product in order to actually compare the two. (*Id.* at 19-20.)

regarding an alleged improper control statement, Klein explained:

[B]ecause it is my understanding that truthful comparative advertising is legally permissible, I wanted to compare the effect of the Perrigo “Compare To” statement, which Rexall alleges is misleading, with another comparative banner statement that was truthful. Thus, for the Control Group, I used alternative packaging with a substitute cardboard banner that said “Different from Osteo Bi-Flex Glucosamine Chondroitin MSM with Joint Shield Ingredients***.” The packaging otherwise used the same colors, fonts and shapes for the banner and kept all other elements of the packaging constant.

...

Perrigo is incorrect in arguing that the Control product I selected was intended to bias the survey in Rexall’s favor. As I observed in my Rebuttal Report, had I used the Control product Perrigo proposes – the Osteo Bi-Flex product with the “Compare To” banner removed, it “would have resulted in no one believing that a comparison had been made. . .” A 0% result in the Control Group would have only inflated the Survey results in Rexall’s favor because there would have been nothing to subtract from the Test Group results. Accordingly, while Perrigo is correct that I considered the option of removing the banner from the Control product and also conferred with Rexall’s counsel concerning this issue, among others, I did not choose that option because it would have made the questionnaire

nonsensical and unfairly biased the survey in Rexall's favor.

(Klein Decl. ¶¶ 10-11 (citations omitted).) Similarly, with respect to the criticism that his "modified" packages failed to satisfy double-blind conditions, Klein stated "it is a well accepted practice to modify product packaging in order to create a control stimulus in false advertising or trademark infringement cases, since such modification allows the survey researcher to isolate the precise reason why certain answers are given in response to the actual product package, while keeping all other elements on the package consistent." (*Id.* ¶ 12.) Klein also provided detailed explanations regarding his review and analysis of the open-ended questions in the context of his analysis of the survey data. (*See id.* ¶¶ 15-18.) Finally, Klein explained why he did not show the participants side by side, or try to further replicate marketplace conditions. (*See id.* ¶¶ 7-8.)

Having reviewed the submissions related to Rexall's expert, including the Klein Declaration, the Court concludes that there is no basis to exclude his testimony under *Daubert*. Perrigo's objections in this particular case regarding the methodology of the study, even if proven and fully credited, clearly go to the weight of the Klein Report, rather than its admissibility. *See Mobil Oil Corp. v. Pegasus Petroleum Corp.*, 818 F.2d 254, 259 (2d Cir. 1987) ("The district court properly admitted these surveys into evidence, despite claims of statistical imperfections by both sides, as those criticisms affected the weight accorded to the evidence rather than its admissibility."); *Aventis Env'tl. Science USA LP v. Scotts Co.*, 383 F. Supp. 2d 488, 514 (S.D.N.Y. 2005) ("Defendants are free to challenge the basis and source for [the proposed expert's] numbers, but a challenge to the facts or data relied upon by [the

proposed expert] does not go to the admissibility of his testimony, but only to the weight of his testimony.") (citing *Concise Oil & Gas P'ship v. La. Interstate Gas Corp.*, 986 F.2d 1463, 1476 (5th Cir. 1993)); *MacQuesten Gen. Contracting, Inc. v. HCE, Inc.*, No. 99-CV-8598 (JCF), 2002 WL 31388716, at *2 (S.D.N.Y. Oct. 22, 2002); *accord Amerisource Corp. v. RX USA Int'l, Inc.*, No. 02-CV-2514 (JMA), 2008 WL 2783355, at *2 (E.D.N.Y. July 15, 2008).

Perrigo has highlighted potential flaws in the survey methodology, but given that there is sufficient indicia of reliability to allow admission of Klein's testimony, "[v]igorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596 (citations and quotations omitted); *accord Borawick v. Shay*, 68 F.3d 597, 610 (2d Cir. 1995) (noting that *Daubert* "advanced a bias in favor of admitting evidence short of that solidly and indisputably proven to be reliable"); *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (D. Vt. 1995) (district court did not abuse its discretion in admitting expert testimony where "[d]isputes as to the strength of his credentials, faults in his use of differential etiology as a methodology, or lack of textual authority for his opinion, [went] to the weight, not the admissibility, of his testimony"). *But see Amorgianos* 303 F.3d at 266 ("[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony."). Accordingly, the Court declines to rule at this juncture that the survey is so unreliable as to be inadmissible.

Because the Klein report is admissible, its conclusion that consumers understand the Compare To Statements to be a claim of equivalency in formulation or result creates an issue of disputed material fact regarding whether the Compare To Statements convey a message of product equivalence in terms of ingredient formulation and/or efficacy that creates a likelihood of consumer deception.

c. Falsity

Perrigo next argues that plaintiff's claims fail to survive summary judgment because, even if the Compare To Statements imply that the parties' products are equivalent, such an implication is not false. In particular, Perrigo contends that the parties' products contain the same amount of AKBA, an active ingredient and the only ingredient alleged by plaintiff in the complaint to be materially different in the products. (Def.'s Mem. at 23-24, 30.)

Rexall, in response, contends that "the AKBA in the Perrigo Products is less efficacious than the AKBA in Osteo Bi-Flex because other boswellic acids in the Perrigo Products detract from the anti-inflammatory effects of the AKBA." (Pl.'s Opp. Mem. at 37.) Rexall has put forth evidence to support this argument, including the declaration of Dr. Croom, a leading U.S. specialist in the field of herbal medicine and the use of botanicals in plant-derived drugs, which states that the Perrigo Products and Osteo Bi-Flex are "significantly different," based on (i) the higher ratio of the AKBA level to boswellic acid content in Osteo Bi-Flex; and (ii) the significantly higher amount of beta boswellic acid in the Perrigo Products, which can reduce the anti-inflammatory activity of the AKBA. (Croom Decl. ¶¶ 8-11.) Based upon the record evidence, including the Croom Declaration, the Court concludes that Rexall has raised a genuine disputed issue of material

fact as to whether any alleged implied assertion of equivalence, in terms of ingredient formulation and/or efficacy in defendant's Compare To Statements, is false.⁸ For this reason, summary judgment is unwarranted on this issue.

d. Materiality

Perrigo next contends that Rexall has not put forth evidence that could support a finding that the Compare To Statements were material to consumers, as required by the Lanham Act. For the reasons discussed below, the Court concludes that summary judgment on this issue is unwarranted because Rexall has put

⁸ Although Perrigo also argues that Rexall failed to specifically plead lack of equivalence on the factual issues now being relied upon and thus should not be able to raise them in opposition to the motion for summary judgment, the Court finds that argument unpersuasive. The Complaint clearly alleges that "the *Boswellia serrata* standardized extract in the Perrigo Products is materially less concentrated and less effective in assisting with joint care than the 5-LOXIN AKBA *Boswellia serrata* Extract in the OSTEOPAIN BI-FLEX Products." (Comp. ¶ 18.) To the extent that the complaint may fail to contain specific allegations regarding every way in which the *Boswellia serrata* extracts are different, such evidentiary detail is not required in the complaint. *See, e.g., Ribis v. Mike Barnard Chevrolet-Cadillac*, 468 F. Supp. 2d 489, 498-99 (W.D.N.Y. 2007) ("It is well established that a plaintiff need not plead evidence in the complaint, and that the specific facts underlying a plaintiff's claim may be brought out during discovery.") (internal citations omitted). Moreover, as Rexall noted, these specific evidentiary claims have been the subject of substantial discovery in this case and, thus, Perrigo cannot claim any surprise or prejudice by the arguments and evidence Rexall has presented in opposition to Perrigo's motion. *See, e.g., Cruz v. Coach Stores*, 202 F.3d 560, 568-69 (2d Cir. 2000).

forth sufficient evidence to create a genuine issue of disputed fact as to the materiality of the “Compare To Statements” to consumers purchasing decisions in the context in which they appear.

It is well settled that “the plaintiff must . . . demonstrate that the false or misleading representation involved an inherent or material quality of the product.” *Time Warner Cable*, 497 F.3d at 153 n.3; *see also Nat’l Basketball Ass’n v. Motorola*, 105 F.3d 841, 855 (2d Cir. 1997) (plaintiff must show that “defendants misrepresented an inherent quality or characteristic of the product”) (internal citations and quotation marks omitted); *Am. Tel. & Tel. Co. v. Winback and Conserve Program, Inc.*, 42 F.3d 1421, 1428 n.9 (3d Cir. 1994) (plaintiff must prove “that the deception is material in that it is likely to influence purchasing decisions”) (citations and internal quotation marks omitted), *cert. denied*, 115 S. Ct. 1838 (1995); *ALPO Petfoods, Inc. v. Ralston Purina Co.*, 913 F.2d 958, 964 (D.C. Cir. 1990) (false or misleading ads must be “material in their effects on buying decisions”); *Taquino v. Teledyne Monarch Rubber*, 893 F.2d 1488, 1500 (5th Cir. 1990) (deception must be “material, in that it is likely to influence the purchasing decision”); *see also* 3 MCCARTHY ON TRADEMARKS § 27:35 at 27-54 (there must be “some showing that the defendant’s misrepresentation was ‘material’ in the sense that it would have some effect on consumers’ purchasing decisions.”).

Reviewing the evidence in the instant case, Perrigo is not entitled to summary judgment on the issue of materiality. First, as noted *supra*, Rexall has created an issue of fact as to whether the Compare To Statements could be understood by a consumer to be conveying a message of equivalence as to the competing products formulation and/or efficacy.

Because a rational trier of fact could conclude that the disputed issues relate to core ingredients and/or efficacy, summary judgment is unwarranted on the issue of materiality. *See, e.g., Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1250 (11th Cir. 2002) (“A plaintiff may establish this materiality requirement by proving that ‘the defendants misrepresented an inherent quality or characteristic of the product.’”) (citation omitted); *see also POM Wonderful, LLC v. Purely Juice, Inc.*, No. CV-07-02633 (CAS), 2008 WL 4222045, at *11 (C.D. Cal. July 17, 2008) (“The fact that Purely Juice’s false advertising pertained to the very nature of its juice product establishes its materiality.”); *see generally Motorola*, 105 F.3d at 855 (“On the present facts . . . the complained-of statements are not material and do not misrepresent an inherent quality or characteristic of the product.”).

Second, not only is an issue of disputed fact on materiality created by the nature of the disputed statements here, but also by the manner in which they are conveyed on the package. As noted by Rexall, the Compare To Statements appear prominently – often highlighted in a banner – on the front panels of the Perrigo Products. Moreover, the statements are in close proximity to product performance claims that are substantially similar to the product performance claims appearing on Osteo Bi-Flex products. *See, e.g., Schick Mfg. v. Gillette Co.*, 372 F. Supp. 2d 273, 286-87 (D. Conn. 2005) (noting that use of statement during valuable television advertising time indicated materiality). Therefore, both the nature and location of the Compare To Statements are sufficient to raise a disputed issue of material fact as to whether the Compare To Statements are material to consumer purchasing decisions. Accordingly, summary judgment on this issue is denied.

In sum, Rexall has set forth sufficient evidence to raise genuine issues of disputed fact on the essential elements of its Lanham Act claim and, therefore, summary judgment on that claim is unwarranted.

2. State Law Claims

Perrigo's sole argument in support of its summary judgment motion on plaintiff's state law claims is that "[b]ecause Rexall's Lanham Act claim fails, the state law claims fail as well." (Def.'s Mem. at 32-33.) As the Court has denied Perrigo's motion for summary judgment on Rexall's Lanham Act claim, and the same substantive standard on the issues raised by Perrigo governs the state claims, the Court likewise denies Perrigo's motion on Rexall's state claims.

B. Perrigo's Counter-Claims

In its counterclaims, Perrigo alleges that Rexall is using various false and misleading statements on its Osteo Bi-Flex products – namely, "No. 1 Dr. Recommended Brand," (Claim 1), "No. 1 Dr. Recommended Joint Care Brand," (Claim 2), "Clinically Tested," (Claim 3), "provides more pure Glucosamine as compared to Glucosamine Sulfate," (Claim 4), "is 10 times more concentrated than typical Boswellia extracts," (Claim 5) and the use of the Arthritis Foundation's name and logo (Claim 6) – violates the Lanham Act and state law.

Rexall has moved for summary judgment on these counterclaims on several different grounds. As set forth below, the Court concludes the following: (1) summary judgment on Claims 1 and 6 is warranted based upon a defense of laches; (2) summary judgment is warranted on Claims 2-4, as well as Claims 1 and 6 (even if they were not subject to the defense of laches), because the

statements cannot be found to be literally false and no extrinsic evidence has been offered (or evidence of deliberate conduct) to support claims of implied falsity; and (3) summary judgment is not appropriate on Claim 5 because Perrigo has submitted evidence (including extrinsic evidence in the form of a consumer survey) that is sufficient to raise genuine issues of material fact on all the essential elements including on the issue of consumer deception, materiality, injury, and causation. The Court will address each of these issues in turn.

1. Defense of Laches on Claims 1 and 6

Rexall contends that Perrigo's causes of action on Claim 1 and Claim 6 are barred by the defense of laches. To establish a defense of laches, Rexall must show (1) that Perrigo knew of the conduct of which it complains, (2) inexcusably delayed in taking action against such conduct, and (3) Rexall would be prejudiced by Perrigo's delay. *See Saratoga Vichy Spring Co., Inc. v. Lehman*, 625 F.2d 1037, 1040 (2d Cir. 1980). Perrigo argues that it did not know and had no reason to know of the falsity of Claims 1 and 6 until the 2007 NAD proceedings exposed them, that Rexall suffered no prejudice from Perrigo's delay, and that public interest weighs against the application of laches. Rexall asserts that defendant has had at least constructive notice of Claims 1 and 6 since at least the late 1990s and has inexcusably delayed taking action against Rexall, resulting in substantial prejudice to Rexall. As set forth below, the Court concludes, based upon the undisputed facts, that Claims 1 and 6 are barred by the defense of laches.

a. Perrigo's Knowledge of the Conduct

The parties disagree on when Perrigo knew or should have known of the conduct of which

it now complains. It is undisputed that Rexall has featured Claims 1 and 6 on packaging and in advertising since the late 1990s and that such materials have been widely disseminated since that time. Perrigo has sold its store-brand version of Osteo Bi-Flex since 2001, and has “admitted that Osteo Bi-Flex is a competitive nutritional supplement that they monitor in the marketplace.” (Ewing Decl., Ex. 3 at 25.) Perrigo, however, contends that it had no reason to know that Claims 1 and 6 were false until the 2007 NAD proceedings.

“[T]he law is well settled that where the question of laches is an issue the plaintiff is chargeable with such knowledge as he might have obtained upon inquiry, provided the facts already known by him were such as to put upon a man of ordinary intelligence the duty of inquiry.” *Johnston v. Standard Mining Co.*, 148 U.S. 360 (1893); *accord Polaroid Corp. v. Polarad Elecs. Corp.*, 182 F. Supp. 350, 355 (E.D.N.Y. 1960), *aff’d*, 287 F.2d 492 (2d Cir. 1961); *see also Constellation Brands, Inc. v. Arbor Hill Assocs., Inc.*, 535 F. Supp. 2d 347, 362 (W.D.N.Y. 2008) (granting summary judgment on laches grounds where plaintiff “either knew, or should have known,” of defendant’s conduct). As to Claim 1 (that Osteo Bi-Flex is the “No.1 Dr. Recommended Brand”), Perrigo argues that

the NAD examined this claim and found that although it was literally true, the contexts in which Rexall used this claim convey that it is because of the product characteristics and purported benefits described nearby that Osteo Bi-Flex is the ‘#1 Dr. Recommended Brand.’ This . . . placed Perrigo on constructive notice that it may have a cause of action for Rexall’s false advertising, and triggered a duty to

inquire into the veracity of Rexall’s other advertising.

(Def.’s Opp. Mem. at 7.) This Court finds this argument unavailing. The NAD proceedings may, in fact, have brought this issue to defendant’s attention, but nothing in the opinion issued by the NAD contains new information that defendant could not have found on its own. Perrigo concedes that it monitored Osteo Bi-Flex in the market and, therefore, surely was aware or should have been aware of Claim 1 and the context in which it was used. Perrigo conceded at oral argument that the information needed to check the veracity of Claim 1 was publicly available and could have been accessed. The NAD’s decision to investigate the matter and the conclusions made by the NAD, therefore, did not provide Perrigo with any previously unknowable facts.

As to Claim 6, Perrigo argues that

It was also in the context of investigating Rexall’s claims following the NAD proceeding that Perrigo learned of Rexall’s deceptive misuse of the Arthritis logo. Specifically, Perrigo learned that although Rexall employed the Arthritis Foundation logo in close proximity to its product claims in a manner that suggested the Arthritis Foundation’s certification of Osteo Bi-Flex’s efficacy, much as toothpaste manufacturers display the American Dental Association symbol on their products, Rexall’s use of the Arthritis Foundation symbol was simply bought and paid for with a donation to the Foundation. Perrigo had no reason to suspect that these deceptions prior to the NAD’s investigation and exposure of Rexall’s advertising misconduct.

(Def.'s Mem. at 8.) The Court finds this argument unpersuasive as well. First, the NAD inquiry did not include Claim 6, so there is nothing in its decision that could have conveyed new information to defendant to support that claim. Second, Perrigo has put forth no evidence to counter plaintiff's claim that this information was public and could have been obtained by Perrigo at any time prior to the NAD proceedings. Perrigo does not contend that any of the information that it references was confidential or could not have been discovered. Therefore, this Court finds that Perrigo had constructive knowledge of its claims as of the late 1990s or 2001, at the latest, when it began marketing its store brand version of Osteo Bi-Flex.

b. Inexcusable delay

The Lanham Act does not provide for a statute of limitations and there is no corresponding federal statute of limitations. Therefore, courts look to "the most appropriate or the most analogous state statute of limitations for laches purposes." *Conopco, Inc. v. Campbell Soup Co.*, 95 F.3d 187, 191 (2d Cir. 1996) (citation and internal quotation marks omitted). The appropriate statute of limitations is the six year fraud statute in the context of false advertising claims. *Id.* Where a party brings a claim after this period has passed, as is the case here, a rebuttable presumption that laches applies is raised. Defendant has offered no explanation for the delay in filing this action, and this Court, therefore, finds that the delay is inexcusable.

c. Prejudice

Rexall has put forth evidence that it has made substantial investments of money and resources in using Claims 1 and 6 in its advertising and packaging. Therefore, Rexall contends that "any injunctive relief granted by

the Court precluding future use of such Statements would have devastating consequences for Rexall. . . [t]he deletion of either Statement from the packaging and advertising for Osteo Bi-Flex would cause consumers to question whether Osteo Bi-Flex remained the 'No. 1 Dr. Recommended Brand' of branded Glucosamine and Chondroitin supplements, or whether Rexall's longstanding relationship with the Arthritis Foundation had soured or ended." (Pl.'s Mem. at 14.) Rexall argues that such harm would have been avoided if Perrigo brought its claims in a timely manner. The Court agrees.

d. Public Interest

Perrigo contends that, even if the elements of the laches defense are met, there is a public interest in preventing false advertising, and, as such, the bar of laches should not be applied. The Second Circuit has found that "the equitable defense of laches may be applied to cases brought under the Lanham Act. . . so long as its application is equitable in light of the public's interest in being free from confusion and deception." *Conopco*, 95 F.3d at 193. Although there is always some public interest in a false advertising claim, courts "must be careful not to define the public's interest in such a manner as to 'effectively swallow the rule of laches, and render it a spineless defense.'" *See Jarrow Formulas, Inc. v. Nutrition Now, Inc.*, 304 F.3d 829, 840 (9th Cir. 2002) (noting that "the public surely has *some* interest in ensuring that all product advertisements are materially accurate. However, if a plaintiff could defeat laches simply by asserting the public's interest in accurate advertising, laches would in effect not be a defense to Lanham Act false advertising claims. . . [I]n order to ensure that laches remains a viable defense to Lanham Act claims, the public's interest will

trump laches only when the suit concerns allegations that the product is harmful or otherwise a threat to public safety and well being.”) (internal citations and quotation marks omitted); *Eppendorf-Netheler-Hinz GmbH v. Enterton Co. Est.*, 89 F. Supp. 2d 483, 488 (S.D.N.Y. 2000) (stating that the Second Circuit “has allowed for the possibility that a particularly compelling public interest in avoiding confusion, where such confusion might compromise public health and safety, could defeat an otherwise valid laches defense in certain circumstances.”) (citing *Conopco*, 95 F.3d at 193-94). Perrigo has made no showing that Rexall’s claims jeopardize public health and safety, and, therefore, this Court declines to find that the public interest weighs against the application of laches.

2. Claims 1-4 and 6

Rexall argues that summary judgment is warranted on Claims 1-4 and 6 because a rational jury could not find that they were literally false and, therefore, the requisite extrinsic evidence to support any claim of implied falsity is lacking. Perrigo made clear in its opposition papers, and confirmed at oral argument (*see* Transcript of May 1, 2009 Oral Argument, at 53-54), that it is only asserting literal falsity with respect to Claims 2 and 3 and is relying upon a theory of implied falsity as to the remaining claims. As set forth below, the Court concludes that summary judgment on Claims 2-4, as well as Claims 1 and 6 (even assuming they were not subject to the defense of laches), is warranted because Perrigo has failed to raise a genuine issue of fact under a theory of either literal or implied falsity.

(i) Literal Falsity

The Second Circuit has clearly stated that “only an *unambiguous* message can be literally false. Therefore, if the language or graphic is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false. There may still be a basis for a claim that the advertisement is misleading, but to resolve such a claim, the district court must look to consumer data to determine what the person to whom the message is addressed find[s] to be the message.” *Time Warner Cable*, 497 F.3d at 158 (internal citations and quotation marks omitted) (emphasis in original). The question of whether an advertising claim is susceptible to more than one reasonable interpretation is a question of law for the court to resolve, similar to the question of whether the terms of a contract are unambiguous. *See, e.g., Am. Council of Certified Podiatric Physicians and Surgeons v. Am. Board of Podiatric Surgery, Inc.*, 185 F.3d 606, 615 n.2 (6th Cir. 1999).

Rexall contends that Perrigo’s claims of literal falsity must fail as to Claims 2 and 3 because the claims are all either literally true or are susceptible to more than one reasonable interpretation, and, therefore, cannot be literally false. For the reasons set forth below, the Court agrees and concludes that summary judgment is warranted on any assertions of literal falsity as to Claims 2 and 3.

(a) Claim 2

Perrigo argues that the claim of “No. 1 Dr. Recommended Joint Care Brand” is false because the NDTI report upon which Rexall based these claims “did not consider all joint care products; it considered only glucosamine dietary supplements.” (Def.’s Opp. Mem. at 18.) Rexall notes that this claim, which has been included in advertisements and

promotion for the product, is always accompanied by the explanation that the “No. 1” ranking is based on the recommendation of “physicians who recommend a branded glucosamine/chondroitin or glucosamine supplement.” (Kamil Decl. ¶¶ 12, 13, Ex. 4, 5.)

Having reviewed the statement in its context, the Court agrees with Rexall that the statement is literally true, or, at least capable of being reasonably interpreted in different ways by different consumers. First, if the statement is read in conjunction with the explanatory note, there is no question that it is literally true. Any attempt by Perrigo to argue otherwise would be frivolous. Thus, Perrigo’s literal falsity claim hinges upon the exclusion of the explanatory note. To the extent that Perrigo suggests that the explanatory note should not be considered in the analysis, the Court disagrees. The Second Circuit has made clear that “‘a district court evaluating whether an advertisement is literally false ‘must analyze the message in full context.’” *Time Warner Cable*, 497 F.3d at 158 (quoting *Castrol Inc. v. Penzoil Co.*, 987 F.2d 939, 946 (3d Cir. 1993)). In other words, the court “‘must consider the advertisement in its entirety and not . . . engage in disputatious dissection.’” *Id.* (quoting *Avis Rent A Car System, Inc. v. Hertz Corp.*, 782 F.2d 381, 385 (2d Cir. 1986)). Here, when the statement is read with the explanatory note, it is literally true.

In any event, even if the statement were not literally true, it is, at a minimum, susceptible to more than one reasonable interpretation. More specifically, given that the advertisement is for a Glucosamine and Chondroitin supplement and given the explanatory note, one reasonable interpretation of the “No. 1 Dr. Recommended Joint Care Brand” claim is that it is referring

to a No. 1 ranking specifically for a branded Glucosamine/Chondroitin or Glucosamine supplement, rather than a top-ranking for all types of joint care products recommended by doctors. Therefore, summary judgment on a theory of literal falsity as to Claim 2 is warranted.

(b) Claim 3

An “establishment claim” is an “advertisement [that] relies either implicitly or explicitly on scientific studies.” *Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp.*, 348 F. Supp. 2d 165, 178 (S.D.N.Y. 2004). To establish a claim of false advertising as to an “establishment claim,” plaintiff must show “that either the tests relied upon do not prove the proposition for which they are cited or that they are ‘not sufficiently reliable to permit one to conclude with reasonable certainty’ that they prove that claim.” *Euro-Pro Operating LLC v. Euroflex Americas*, 08-CV-6231 (HB), 2008 WL 5137060, at *11 (S.D.N.Y. Dec. 8, 2008) (quoting *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991)).

Perrigo contends that Claim 3 is an “establishment claim.” The Court agrees that Claim 3 is an “establishment claim” because it asserts that the product and/or its ingredients have been “clinically tested.” See *C.B. Fleet Co., Inc. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 436 (4th Cir. 1997) (stating that the relevant question is “whether the advertisement made an assertion of test validation to the consumer public”).

Perrigo further argues that Claim 3 is literally false because the test upon which

Rexall relies in making this statement does not support the statement, in that it was not testing for the formulation upon which the claim appears; “[r]ather, only the principal ingredients in Osteo Bi-Flex, glucosamine and chondroitin sulfate, have been the subject of clinical testing.” (Def.’s Opp. Mem. at 20.) Rexall notes that this claim only appears on the Osteo Bi-Flex website – not on the product’s packaging – and that the webpage “discusses at some length the various formulations of Osteo Bi-Flex and its primary ingredients (Glucosamine, Chondroitin and 5-LOXIN) and never specifies which of these has been clinically tested.” (Pl.’s Reply Mem. at 19.) Rexall further argues that, in any event, the claim is susceptible to more than one reasonable interpretation, including that the principal ingredients of the product or prior formulations (not the product itself) were subject to clinically testing and it is undisputed that prior formulations of Osteo Bi-Flex, as well as the ingredients Glucosamine/Chondroitin and 5-LOXIN, have all been the subject of clinical testing.

Although Perrigo contends that Claim 3 is literally false because “clinically tested” unambiguously refers to the current formulation of Osteo Bi-Flex, the Court finds that argument unpersuasive. The statement does not refer to the current formulation of Osteo Bi-Flex and simply appears in isolation as a point heading. The Court concludes that the claim “clinically tested” is susceptible to more than one reasonable interpretation and, given the context in which it is used, could be reasonably understood to refer to a prior formulation or to the current active ingredients. In short, this statement is not unambiguous, and, as a result, may not be actionable under the Lanham Act under a theory of literal falsity. Therefore, summary judgment on a theory of literal falsity as to Claim 3 is warranted.

(ii) Implied Falsity as to Claims 1-4 and 6

Rexall contends that Perrigo cannot support a claim of implied falsity on Claims 1-4 and 6 because defendant has not put forth any extrinsic evidence of consumers’ perception of the claims, as required under the law. For the reasons set forth below, the Court agrees and concludes that, given the absence of extrinsic evidence to support a claim of implied falsity and the absence of evidence of deliberate conduct, summary judgment on Claims 1-4 and 6 under a theory of implied falsity is warranted.

It is well settled that, when a plaintiff is seeking to proceed on a claim of implied falsity, “a plaintiff must demonstrate, by extrinsic evidence, that the challenged commercials tend to mislead or confuse consumers.” *Johnson & Johnson*, 960 F.2d at 297. The reason for this rule, as the Second Circuit has emphasized, is clear – “where the advertisement does not unambiguously make a claim, ‘the court’s reaction is at best not determinative and at worst irrelevant.’” *Time Warner Cable, Inc.*, 497 F.3d at 158 (citing *Am. Home Prods.*, 577 F.2d at 166). Thus, courts routinely grant summary judgment in a defendant’s favor on implied falsity claims when such extrinsic evidence, usually in the form of a consumer survey, is lacking. *See, e.g., New Sensor Corp. v. CE Distribution LLC*, 303 F. Supp. 2d 304, 316-17 (E.D.N.Y.) (granting summary judgment on implied falsity claim given the absence of survey evidence), *aff’d*, 121 Fed. Appx. 407 (2d Cir. 2004); *Malaco Leaf, A.B. v. Promotion in Motion, Inc.*, 287 F. Supp. 2d 355, 379 (S.D.N.Y. 2003) (granting summary judgment on implied falsity and noting “[w]hen an advertisement is not literally false, but rather is ambiguous or implicitly false, a plaintiff can only establish a claim of false advertising through a survey”); *see also Johnson &*

Johnson Vision Care, Inc. v. Ciba Vision Corp., 348 F. Supp. 2d 165, 184 (S.D.N.Y. 2004) (“To the extent that Plaintiff contends that CIBA’s overall health superiority claim is impliedly false, CIBA’s Rule 52(c) motion for judgment in its favor on partial findings is granted, as Plaintiff has neither introduced the requisite extrinsic evidence of consumer reaction showing that CIBA’s promotional materials tend to mislead or confuse the target audience of eye care professionals, nor adequately demonstrated that CIBA has intentionally tried to deceive the public in an egregious fashion as to the health benefits of O₂OPTIX.”).

Perrigo argues that the NAD and National Advertising Review Board (“NARB”) decisions, themselves, constitute extrinsic evidence that the statements are misleading. The Court finds this argument unpersuasive. The Second Circuit has clearly stated that the purpose of extrinsic evidence that a statement is misleading to consumers is largely to avoid having “the judge determine, based solely upon his or her own intuitive reaction, whether the advertisement is deceptive. Rather, as we have reiterated in the past, ‘[t]he question in such cases is – what does the person to whom the advertisement is addressed find to be the message?’” *Johnson & Johnson*, 960 F.2d at 297-98 (citation and internal quotation marks omitted) (emphasis in original). Simply substituting the findings of the NAD and NARB decision-makers for that of the district judge would not be consistent with the Second Circuit’s guidance. Moreover, the NAD and NARB decisions make no finding of consumer deception, nor do they make a finding of a likelihood of consumer deception. In fact, to the extent Perrigo is attempting to rely upon such findings for the truth of the matter asserted, Perrigo has failed to explain how the NAD and NARB decisions could even be admitted

under the Rules of Evidence. These findings, like judicial findings, are generally characterized as inadmissible hearsay that cannot be used to prove the truth of the matter asserted. *See, e.g., Blue Cross and Blue Shield of N.J., Inc. v. Philip Morris, Inc.*, 141 F. Supp. 2d 320, 323 (E.D.N.Y. 2001) (“[j]udicial findings in other cases proffered as extrinsic evidence are generally characterized as inadmissible hearsay”). Finally, Perrigo has been unable to point to any case in the United States, either in its brief or at oral argument, where NAD and NARB findings have been found to constitute admissible extrinsic evidence that could support an implied falsity claim. As noted above, cases that have found sufficient evidence of consumer deception have relied upon surveys of potential consumers or evidence provided by consumers who were actually misled. Although the use of other extrinsic evidence of likely consumer deception is not foreclosed, defendant has put forth no such admissible evidence. Therefore, the Court finds that Perrigo has not put forth any admissible extrinsic evidence for Claims 1-4 and Claim 6.

Perrigo contends, in the alternative, that it does not need to provide extrinsic evidence because it “adequately demonstrates that [Rexall] has intentionally set out to deceive the public,’ and the defendant’s ‘deliberate conduct’ in this regard is of an egregious nature.” (Def.’s Mem. at 11 (quoting *Johnson & Johnson Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298-99 (2d Cir. 1992))). However, as discussed below, Perrigo has failed to support this conclusory assertion of deliberate conduct or bad faith with evidence from which a rational jury could make such a finding.

As a threshold matter, Perrigo does not even attempt to argue that Rexall had any

intent to deceive at the time it adopted the statements at issue. Instead, Perrigo primarily relies upon the contention that “Rexall was advised of the misleading nature of its advertising by the NAD in July 2007 and, by Rexall’s own admission, the offending statements were not changed until June 2008 – nearly 11 months later.” (Def.’s Response to Pl.’s 56.1 Statement ¶ 42.) However, there are several problems with this assertion given the undisputed facts. First, Rexall appealed the NARB decision in March 2008 and there is no evidence of any deadlines by the NAD or NARB for compliance with their recommendations. Second, the changes recommended by the NAD and NARB were made no later than a few months after Rexall received the NARB appeal decision in March 2008. Third, Rexall went beyond the NAD’s recommendations by discontinuing Claims 2, 3, and 4. In short, based upon the undisputed facts, no rational jury could conclude that Rexall’s response to the NAD and NARB recommendations supports a finding of intentional misconduct of an egregious nature, or bad faith.

Similarly, although Perrigo asserts in a conclusory fashion that “Rexall’s own employees with responsibility for the advertising in question admitted that certain of the advertising was known to be misleading.” (Def.’s Response to Pl.’s 56.1 ¶ 42), there is no evidence in the record to support that conclusory assertion and create a genuine issue of fact for trial. For example, Perrigo points to deposition testimony by a former brand manager for Osteo Bi-Flex stating that the use of the Arthritis Foundation was misleading as presented. However, this was a retrospective assessment by a former employee, who was terminated in 2005, not an admission that Rexall knowingly misled consumers. The testimony was as follows:

Q. Do you think it was misleading at all to have the product logo on the packaging when the product did not treat arthritis?

* * *

A. It was typical, a lot of other companies used it. Do I typically think it was misleading? Yes, it probably was. To the uneducated consumer, it probably was, but we never made any drug claims.

(Marcotte Decl., Ex. 13, at 147.) That statement cannot reasonably support a finding by a rational jury that Ms. Whitaker or anyone else intended to mislead customers through the authorized use of the Arthritis Foundation logo.⁹

In sum, Perrigo attempts to point to two pieces of “evidence” to support its argument that Rexall intended to deceive the public: (1) the NAD and NARB decisions; and (2) Rexall’s own documents and testimony, which defendant contends indicate intentional misrepresentation with respect to certain counterclaims. However, Rexall puts forth evidence that all of the NAD and NARB recommendations were put into place within a few months of the NARB appeal decision in March 2008. (Macotte Decl., Ex. 2 at 16-17, Ex. 3 at 6; Kamil Reply Decl., ¶¶ 10-14.) Perrigo has put forth no evidence to counter this claim. Nor does Perrigo point to any specific part of “Rexall’s own documents and

⁹ In addition, although cited by Rexall, there is nothing in the deposition testimony of Dr. Angelica Vrablic regarding Claims 3 and 4, or the Rexall 2002-05 strategic plan that refers to the Arthritis Foundation logo, which provides any evidence of intentional misconduct or bad faith.

testimony” to support its contention that such documents and testimony evidence an intent to deceive consumers. Perrigo’s conclusory statement is insufficient to support a finding of intentional deception necessary to circumvent the requirement of extrinsic evidence that the statements are false or misleading. *See, e.g., Resource Developers, Inc. v. The Statute of Liberty-Ellis Island Found., Inc.*, 926 F.2d 134, 140-41 (2d Cir. 1991) (“Resource must demonstrate that Dettra set out to intentionally deceive flag purchasers by representing that it was affiliated with the Foundation. Resource, however, failed to produce evidence of Dettra’s intent to deceive its customers. . . . We have not hesitated to affirm a summary judgment when the only proof proffered in opposition amounts to nothing more than speculation and conjecture.”)

Accordingly, because of the absence of extrinsic evidence to support a claim of implied falsity and the absence of evidence of deliberate conduct, summary judgment is appropriate on Claims 1-4 and 6 under a theory of implied falsity.¹⁰

3. Claim 5

With respect to Claim 5, Perrigo contends that the claim that the key ingredient in the Osteo Bi-Flex is ten times more concentrated, “juxtaposed with the performance claim that patients taking the ingredient showed improvement in joint comfort conveys the false and misleading claim that because consumers are getting a more ‘concentrated’

¹⁰ Although Rexall has raised other grounds for summary judgment on Claims 1-4 and 6, the Court need not address those issues because the Court has already determined that these claims cannot survive summary judgment for the reasons discussed *supra*.

version of *Boswellia serrata* by taking Rexall’s product as opposed to other typical *Boswellia* extracts, Osteo Bi-Flex provides greater performance benefits (*i.e.*, efficacy on knee comfort and mobility and increased walking distance, etc.) than, or is superior to, other products. Rexall has no support for this claim.” (Def.’s Opp. Mem. at 13.) Perrigo points to, among other things, the Ossip Survey to support this argument. Specifically, defendant argues that “the Ossip Survey found that the ‘10 Times More Concentrated’ Claim ‘causes a meaningful proportion of prospective consumers to think that Osteo Bi-Flex provides greater performance benefits than, or is superior to, other products.’”¹¹ (Def.’s Opp. Mem. at 14 (quoting Marcotte Decl., Ex. 6, at 1).)

¹¹ The Ossip Survey found that “[o]f those exposed to the claim, 55% thought the product would be better, compared with 38% among those not exposed to the . . . claim.” (Marcotte Decl. Ex. 6, at 5, 9.) Rexall contends that the Ossip Survey “is ultimately subject to exclusion under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 594-95 (1993) and its progeny because it is riddled with deficiencies.” (Pl.’s Mem. at 6 n.4.) However, Rexall did not seek to exclude the survey from evidence at this time and reserved its right to make a motion in limine in the future, if necessary. (*Id.*) Thus, construing the evidence in the light most favorable to Perrigo, the Ossip survey is sufficient to preclude summary judgment on the issue of consumer confusion. *See, e.g., Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer. Pham. Co.*, 290 F.3d 578, 594 (3d Cir. 2002) (finding survey evidence showing that 15% of the respondents were misled was sufficient to establish “actual deception or at least a tendency to deceive a substantial portion of the intended audience”) (internal quotation marks omitted). However, as discussed *infra*, the Court must still examine the issues of materiality and causation.

Rexall argues that summary judgment on Claim 5 is warranted because (1) Perrigo cannot establish the essential element of materiality, and (2) Perrigo has no evidence to show that any injury was caused by Rexall's advertising. As set forth below, the Court disagrees, and concludes that Perrigo has presented sufficient evidence on these elements (and all other elements) to create genuine issues of material fact that survive summary judgment on Claim 5.

a. Materiality

To survive Rexall's motion for summary judgment with respect to Claim 5, Perrigo must show that the statement is material. Rexall argues that the Ossip survey "confirms that there is no statistically significant difference in the levels of purchase interest manifested by respondents exposed to an altered version of Osteo Bi-Flex packaging including Statement 5 and respondents exposed to a similar stimulus from which that Statement was deleted."¹² (Pl.'s Mem. at 27.) Rexall thus argues that the "survey therefore establishes beyond any doubt that, in fact, Rexall Advertising Statement 5 is *not* likely to influence consumer purchasing decisions and that Perrigo therefore cannot establish the essential element of materiality on the prong of its Counterclaim." (*Id.*)

The Court finds this argument to be unpersuasive. As noted above, the Ossip Survey found that the "10 Times More Concentrated" claim "causes a meaningful proportion of prospective consumers to think

that Osteo Bi-Flex provides greater performance benefits than, or is superior to, other products." (Marcotte Decl., Ex. 6, at 4.) Although the survey concluded that consumers who saw the claim were not statistically significantly more likely to express interest in purchasing Osteo Bi-Flex, the survey's inability to find evidence that any confusion influenced the purchasing decision does not require a finding of immateriality as a matter of law. In other words, the fact that a portion of the survey may undermine Perrigo's position regarding materiality does not mean that materiality cannot be proven by other means. Unlike on the issue of consumer confusion, materiality need not be proven by extrinsic evidence such as consumer surveys. Moreover, as noted in connection with Rexall's claim, materiality may be proven by showing that the misrepresentation related to an inherent characteristic of the product. *See S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 238 (2d Cir. 2001); *Motorola, Inc.*, 105 F.3d at 855; *accord Vidal Sassoon, Inc. v. Bristol-Myers Co.*, 661 F.2d 272, 278 (2d Cir. 1981). In the instant case, a reasonable jury could conclude that the "10 Times More Concentrated" Statement relates to an inherent characteristic or quality of the product – namely, its composition (in terms of the quantity of its active ingredient) and/or effectiveness – such that it would be material to any consumer. *See, e.g., Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 312 (1st Cir. 2002) (claims regarding degree of content of primary ingredient are material); *HipSaver Co. v. J.T. Posey Co.*, 490 F. Supp. 2d 55, 69 (D. Mass. 2007) (claims of effectiveness are material); *Performance Indus., Inc. v. Koos, Inc.*, Civ. A. No. 90-6435, 1990 WL 161253, at *5 (E.D. Pa. Oct. 17, 1990) (same). Therefore, defendant has raised a genuine issue of material fact as to whether Claim 5 was

¹² The survey resulted in a finding that "those seeing the 10 times claim had a mean interest level [in purchasing the product] of 6.96 out of a maximum of 10, compared with 6.6 among those not seeing that claim." (Marcotte Decl. Ex. 6, at 4.)

material. As a result, summary judgment on this basis is denied.

c. Injury and Causation

To survive summary judgment on a false advertising claim under the Lanham Act, a party must also make a showing of both an injury and a causal link between the injury and the allegedly false advertising. *See e.g., Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 694 (2d Cir. 1994) (“[L]ikelihood of injury and causation will not be presumed but must be demonstrated in some manner.”) (citation and internal quotation marks omitted); *accord Air Turbine Tech., Inc. v. Atlas Copco AB*, 410 F.3d 701, 709 (Fed. Cir. 2005); *Hickson*, 357 F.3d at 1260; *Johnson & Johnson Vision Care, Inc. v. 1-800 CONTACTS, Inc.*, 299 F.3d 1242, 1247 (11th Cir. 2002).

Rexall contends that Perrigo has provided no evidence that it has suffered any damages as a result of Rexall’s Claims, and, therefore, cannot recover monetary damages under 15 U.S.C. § 1117(a). Rexall points to the fact that Perrigo “never attempted to quantify such damages [in its initial disclosure], nor did its original and supplemental interrogatory responses [do so]. Indeed, Perrigo averred in both of its interrogatory responses that its claims for monetary relief would be specified in the report of its damages expert, . . . but that report says nothing about the issue of damages and contains only a perfunctory one-page claim for Rexall’s alleged profits.” (Pl.’s Mem. at 30.)

Perrigo argues that it “need not prove specifically that it has been injured by Rexall’s claims. Such injury exists when, as here, claims of comparative superiority are made . . . While Rexall’s advertising does not specifically mention a specific competitor,

like Perrigo, it claims, as demonstrated above, that it is competitively superior to other products . . .” (Def.’s Mem. at 25.)

Injury may be presumed “where [the] plaintiff demonstrates a likelihood of success in showing literally false [the] defendant’s comparative advertisement which mentions [the] plaintiff’s product by name.” *Castrol v. Quaker State Corp.*, 977 F.2d 59, 62 (2d Cir. 1992). Moreover, even if the product is not mentioned by name, such injury also can be presumed where “given the nature of the market, it would be obvious to the viewing audience that the advertisement is targeted at the plaintiff, even though the plaintiff is not identified by name.” *Time Warner Cable*, 497 F.3d at 148.

The statement at issue here is the “10 Times More Concentrated” claim. The claim does seem to suggest an advantage over competing products and, construing the evidence in the light most favorable to Perrigo and drawing all reasonable inferences in its favor, Perrigo has created an issue of disputed material fact as to whether the nature of the market is such that it is “obvious” that the claim targets Perrigo products and, thus, that injury should be presumed. Therefore, summary judgment is unwarranted on the issue of injury and causation.¹³

¹³ Rexall also argues that it is entitled to summary judgment from any money damages sought on this claim (as opposed to injunctive relief) because Perrigo lacks essential evidence to support such relief. As discussed *supra*, there is no evidence to support a showing of willful intent to deceive consumers and, thus, Perrigo cannot recover any accounting of Rexall’s profits as a matter of law. *See, e.g., Haritatos v. Hasbro, Inc.*, No. 6:05-CV-930, 2007 WL 3124626, at *6-7 (N.D.N.Y. Oct. 23, 2007) (granting summary judgment on claim for accounting); *accord Information Superhighway, Inc. v. Talk Am., Inc.*, 395 F. Supp.

IV. CONCLUSION

* * *

For the reasons stated above, the Court (1) denies Perrigo's summary judgment motion on Rexall's claims in its entirety, and (2) grants in part and denies in part Rexall's motion for summary judgment on defendant's counterclaims – namely, summary judgment is granted on Claims 1-4 and 6 and denied on Claim 5.

The Court will conduct a telephonic conference on Monday, September 28, 2009 at 2:00 p.m. in order to discuss any supplemental submission by Perrigo on monetary damages, to schedule a date for submission of the joint pre-trial order, and to schedule a trial date. Counsel for plaintiff shall initiate the conference by first getting defendant on the line, and then contacting Chambers at the appropriate time.

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SO ORDERED.

JOSEPH F. BIANCO
United States District Judge

Dated: September 10, 2009

2d 44, 57 (S.D.N.Y. 2005); *We Media, Inc. v. Gen. Elec. Co.*, 218 F. Supp. 2d 463, 474-75 (S.D.N.Y. 2002). However, Perrigo could recover monetary damages to recover profits from Perrigo's lost sales that resulted from the misleading statement, if proven. Perrigo has attempted to reserve the right to supplement its expert report as necessary, presumably to include evidence of such damages. (Def.'s Response to Pl.'s 56.1 ¶¶ 40-41). The Court will allow Perrigo to make an application to submit a supplemental submission on monetary damages relating to profits from Perrigo's lost sales.